: 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Integrated Pain Management Programs

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Integrated Pain Management Programs,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: Submission Deadline on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E77D

Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT:

Jenae Benns, Telephone: 301-427-1496 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Integrated Pain Management Programs*. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Integrated Pain Management Programs*, including those that describe adverse events. The entire research protocol is available online at: https://effectivehealthcare.ahrq.gov/products/integrated-pain-management/protocol

This is to notify the public that the EPC Program would find the following information on Integrated Pain Management Programs helpful:

- A list of completed studies that your organization has sponsored for this indication.
  In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
    - *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions,

inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/email-updates.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQs)

KQ1: What are the effectiveness and harms of integrated or comprehensive pain management programs for Medicare beneficiaries with complex acute/subacute pain or chronic, non-active

cancer pain? Population subgroups of interest include those with disabilities (including ESRD), prior substance use disorder, psychological co-morbidities (including suicidal behaviors), and degree of nociplasticity.

KQ2: Have any of the following factors been evaluated and/or shown to impact outcomes in studies of comprehensive or integrated pain management models?

a. **Treatment delivery** including session formats (group, one-on-one), duration, intensity and frequency of sessions, number of sessions; general structure and scope of sessions
b. **Treatment components** (e.g., medication review and/or management, including transition from opioid to nonopioid medications; psychological support or mental health services; physical reconditioning, such as physical therapy and occupational therapy; use of complementary and integrative medicine treatments; patient education; use of medical procedures or devices)
c. **Care provision**
    i. Care coordination methods or decision support
    ii. Provider types involved
    iii. Personalization, care pathways
d. **Program characteristics**
    i. Program emphasis/goals
    ii. Target population
    iii. Referral sources
    iv. Staffing characteristics (e.g., turn over)

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

PICOTS	Inclusion	Exclusion
Population	Medicare beneficiaries (i.e., adults ≥65 years old and those under 65 years old who qualify for Medicare due to disability including ESRD) with complex acute/subacute pain[a] or chronic non-active cancer pain[b]. In the absence of publications in Medicare populations, studies of adults with these types of pain will be considered. Population subgroups of interest include those with disabilities (including ESRD), prior substance use disorder, psychological co-morbidities (including suicidal behaviors), degree of nociplasticity[c]	• Patients undergoing end-of-life care, terminally ill (e.g., hospice) patients; those under supervised palliative care • Young, non-disabled populations

PICOTS	Inclusion	Exclusion
Intervention	Pain management programs that address the biopsychosocial model of pain and include: • Multidisciplinary (interdisciplinary) teams that at a minimum have the following components available: pharmacotherapy review and/or management, psychological care (mental health services), and physical reconditioning (e.g., PT, OT); studies may also include other components in addition to these; ***and*** • Description of care coordination, case management or mechanisms of multidisciplinary, interdisciplinary collaboration and communication Integrated pain management programs (IPMPs) will be defined as those that include the above and are based in primary care. Comprehensive pain management programs (CPMPs) will be defined as those including the above but are not based in primary care.	• Unimodal pain management • Pain management confined to a single provider type, practice, or isolated method of management • Programs focused on functional restoration and/or occupational health focused on return to work such as work hardening programs, unless they are specifically done in a Medicare eligible population or are clearly applicable to the Medicare population • Programs in very young and non-disabled populations (e.g. military populations) • Studies evaluating incremental value of adding a single treatment modality to another single treatment modality (e.g. addition of CBT to PT). • Post-operative or post-trauma rehabilitation programs
Comparator	Any	None
Outcome	**Patient oriented outcomes** • ***Primary:*** Pain, function (focus on "success" if reported), opioid use • ***Secondary***: HRQOL, emotional function (e.g., depression, anxiety), patient satisfaction, global improvement **Harms, adverse events, unintended consequences** **Program-related outcomes** • Utilization (e.g., pain-related hospital/ED visits or short-term skilled nursing facility use, long term care facility or institutional care transfer, Medicaid enrollment)	**Patient-oriented outcomes** • Non-validated instruments for outcomes (e.g., pain, function, HRQOL, depression, etc.) • Intermediate outcomes (e.g., range of motion, physical strength, etc.)

PICOTS	Inclusion	Exclusion
Timing	Duration of follow up: Focus on persistence of effects evaluated short term (1 to <6 months), intermediate term (≥6 to <12 months) and long term (≥12 months) following intervention	
Setting	Outpatient, inpatient, institutional residence	• Inpatient or outpatient settings exclusively providing treatment for SUD/OUD or tertiary care, hospice, or similar settings
Study design, publication type	Inclusion will focus on RCTs. Prospective cohort studies that control for confounding will be considered if RCTs are not available. Comparative cohorts that do not control for confounding will be considered if cohorts controlling for confounding are not available. In the absence of comparative studies, single arm (e.g., case series, pre-post studies) will be considered if they are clearly relevant to the Medicare population.	• Case reports • Case series (unless no comparative studies) • Case-control studies, cross-sectional studies • Conference proceedings, editorials, letters, white papers, citations that have not been peer-reviewed

CBT = Cognitive Behavioral Therapy; ED = emergency department; ESDR = end stage renal disease; HRQOL = Health-related quality of life; OT = occupational therapy; OUD = opioid use disorder; PICOTS = population, intervention, comparator, outcomes, timing, study design; PT = physical therapy; RCT = randomized control trial; SUD = substance use disorder.

[a] Complex acute or subacute pain: Patients with acute pain (<6 weeks duration) or subacute pain (6 weeks to 12 weeks duration) who are at risk of developing chronic pain).

[b] Chronic, nonactive cancer pain (based on Mersky 1994): Pain that persists for at least three months and is not associated with [active] malignant disease"; pain could, however, be resultant from a previous malignancy that is no longer active.

[c] The term nociplasticity has been used to describe pain resulting from altered nociception without underlying tissue damage resulting in hypersensitivity (e.g., fibromyalgia). Many pain conditions may have a nociplastic component. Some additional terms used in the literature include centralized pain and amplified pain.

Dated: November 13, 2020.

Marquita Cullom,

Associate Director.

[FR Doc. 2020-25451 Filed: 11/18/2020 8:45 am; Publication Date: 11/19/2020]